A Prospective Observational Study on Assessment of the Soluble Urokinase Plasminogen Activator Receptor in Adult Patients Undergoing Major Non-cardiac Surgery (SPARSE)

STUDY INFORMATION SHEET FOR PATIENTS

TITLE OF STUDY
A Prospective Observational Study on Assessment of the Soluble Urokinase Plasminogen Activator Receptor in Adult Patients Undergoing Major Non-cardiac Surgery (SPARSE)

PRINCIPAL INVESTIGATOR
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PURPOSE OF STUDY

Dear Madam, Dear Sir,

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

The purpose of this study is to investigate if soluble urokinase plasminogen activator receptor (suPAR) measured preoperatively and immediately after surgery can predict the risk of future complications and post-operative mortality in adults following major non-cardiac surgery. There is a blood test that can measure the suPAR levels. The knowledge gained from this study may allow physicians to optimize the perioperative management to the needs of future patients.

STUDY PROCEDURES

What does your participation involve?

Should you agree to participate to this study, we will collect 5 mL of blood (1 tea spoon) twice, immediately after arrival to the Operating Room and at the Post-Anesthesia Care Unit.

With the exception of the sampling of a tea spoon of blood once, participation in the study will not affect in any other way the medical care you are going to receive. If you decide not to take part in this study, it will not affect in any way your treatment or care.

Participant's Initials: _____

Withdrawal from the study

Even though you have agreed to participate, you may leave the study whenever you wish without any effect on your medical care and without having to offer any explanation. If you decide to withdraw from the study no further data will be collected, while already collected, encoded data (identified by a number) will be anonymized. Analysis may be performed up to the point of data collection.

Privacy and use of clinical information

To carry out the study it will be necessary to consult your medical record and collect some of the information that appears in it. Your agreement to participate in the study will authorize study personnel to consult and process the information in the following manner:

- Study participants will be identified by a number (encoding). The key linking the study number to your personal identification will be kept confidential and will be accessible by authorized personnel only.
- Anonymized information, i.e. only identified by a number and without link to personal identification will be stored in a computerized database protected through personalized and confidential username and password. No data concerning personal identification will be stored in this computer database.
- For purposes of monitoring, the investigators, members of the relevant ethical board, or regulatory authorities will be allowed to access all study documents, including identifiable information. All handling of personal data will comply with the Good Clinical Practice Guidelines and strictly follow the legal and national requirements for data protection.

Publication of the study findings

The anonymized findings of the study will be presented at medical conferences and published in medical journal(s). All participating investigators will be listed in the publication(s) and will be able to provide a copy upon request.

Finally, we would like to draw your attention to the fact that this informative consent document refers only to your participation in the study.

Participant's Initials: _____

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CONSENT FORM

Please initial all boxes

1. I confirm that I have read and understand the information sheet for the above study. I have had enough time to consider the information, the opportunity to ask questions, and I have received satisfactory answers.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐
3. I understand that my personal data will stored locally in encoded and in anonymized form.	☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by the investigators or members of the relevant ethical board, or regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
5. I agree to take part in the above study.	☐

CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____

Participant's Initials: _____